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**IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP, KBI INC.,
and KBI-E INC.,

Plaintiffs and
Counterclaim Defendants,

v.

HANMI USA, INC., HANMI
PHARMACEUTICAL CO., LTD., HANMI
FINE CHEMICAL CO., LTD, and HANMI
HOLDINGS CO., LTD.,

Defendants and
Counterclaim Plaintiffs.

Civil Action No. 11-760 (JAP)(TJB)

Judge Joel A. Pisano
Magistrate Judge Tonianne J. Bongiovanni

**HANMI'S OPPOSITION TO PLAINTIFF'S MOTION TO PRECLUDE
HANMI'S EXPERT DR. GENCK FROM RELYING ON CERTAIN
NON-INFRINGEMENT OPINIONS AND EVIDENCE CONCERNING "HYDRATES"**

Hanmi opposes AstraZeneca's motion to preclude Hanmi's expert Dr. Genck from presenting certain opinions and evidence from his second expert report relating to Hanmi's non-infringement of the asserted claims. AstraZeneca has no basis to seek preclusion of Dr. Genck's testimony. The non-infringement analyses set forth in Dr. Genck's second report are not new, but rather are now informed by the present case record (the complete record of Hanmi's October 11, 2011 Motion for Summary Judgment No. 4, and Hanmi's Second Amended Contentions). Dr. Genck's opinions also respond to AstraZeneca's evolving infringement contentions and therefore are both timely and non-prejudicial.

This Court granted Hanmi's motion to amend its contentions to "assert that its proposed product does not infringe because the claims do not encompass hydrated forms of the claimed salts of esomeprazole." (*See* D.I. 269, p. 3). Now, AstraZeneca effectively seeks reconsideration of the Court's Order by attempting to preclude, *in limine*, Hanmi's non-infringement evidence – the very evidence this Court permitted Hanmi to add to its contentions. AstraZeneca cannot seek reconsideration of the Court's Order under the guise of a motion *in limine*. The time for seeking reconsideration has long since passed.

I. Dr. Genck's Opinions Timely Respond to AstraZeneca's Evolving Infringement Contentions And Involve No Claim Term Interpretation

Dr. Genck's opinions and evidence are directed to the non-infringement of Hanmi's proposed products and are based upon the scope of the asserted '504 and '192 patent claims as urged by AstraZeneca, in view of the present case record. That record includes the briefing, exhibits, and arguments on Hanmi's Motion for Summary Judgment No. 4 (D.I. 116), Hanmi's amended contentions, (D.I. 239), and AstraZeneca's evolving infringement contentions.

AstraZeneca argues that Dr. Genck's report contains new claim construction arguments. (D.I. 293, p. 5). In particular, AstraZeneca urges that Dr. Genck and Hanmi's non-infringement position is based on a claim construction of the terms "solid-state" and "alkaline salts of [esomeprazole]." (D.I. 293, p. 6). Neither argument has merit. AstraZeneca continues in its failure to distinguish between claim term interpretation on the one hand, and the breadth of claim scope as it relates to the public notice function of claims on the other. As shown below, AstraZeneca created the illusory claim construction issue to which it now seeks preclusion of any responsive evidence by Hanmi. Its transparent tactics should be rejected.

In its motion to amend its contentions, Hanmi repeatedly urged non-infringement of the asserted claims, based on a claim scope that was neither described nor enabled. (*See* D.I. 238-1). Both before and after Hanmi's motion, Hanmi informed AstraZeneca that its position was not based on the construction of *any* specific claim term. (*See, e.g.*, D.I. 261, and Exhibit A of D.I. 261 at p. 1). Hanmi told AstraZeneca there was simply no claim term to be construed, because its amended contentions were based on claim *scope*. AstraZeneca seemed to understand this based on statements made in its opposition to Hanmi's motion.¹ Nevertheless, AstraZeneca persisted in its argument that a new claim construction issue was raised through Hanmi's non-infringement arguments. (*See* D.I. 244).

In granting Hanmi's Motion to Amend, the Court acknowledged AstraZeneca's request to extend the trial schedule based on the purported "claim construction" issue, but stated:

According to Astra, this is required in order to resolve an alleged claim construction issue that arises as a result of Hanmi's proposed amendment. ***Astra, however, does not identify any specific term***

¹ *See, e.g.* D.I. 244-1, p.7 ("But, any reasonable reading of Hanmi's Motion to Amend reveals that it argues a new claim scope construction. Indeed, the words "claim scope" appear numerous times in Hanmi's motion.").

for which construction is required, but rather generally refers to the issue raised by Hanmi as one involving "claim scope."

(D.I. 269, p. 2) (emphasis added).

Recognizing that its cries of "new claim construction issue!" would fail without a specific claim term to be construed, AstraZeneca searched for a term in need of construction after the Court's Order on January 23, 2013. It did not take long. Just weeks later, in the opening expert report of Prof. Byrn on February 19, 2013, AstraZeneca argued for the first time in this litigation that the terms "solid-state" and "alkaline salts [of esomeprazole]" encompassed hydrated forms.² (See, e.g., Byrn Opening Report (D.I. 294-2) ¶¶ 29, 106-117). At no time prior to Prof. Byrn's report had any party in this litigation proposed a claim term construction of "solid-state" or "alkaline salts [of esomeprazole]" that specifically included *hydrates*.

Yet Dr. Genck's March 25 report did no more than respond to AstraZeneca's new constructions of "solid-state" and "alkaline salts [of esomeprazole]." Dr. Genck's opinions were based on: 1) Hanmi's contentions alleging non-infringement of the claims to the extent asserted to encompass hydrates (which contentions were specifically permitted by this Court); and 2) AstraZeneca's newly-minted construction of "solid-state" as literally encompassing *hydrates*. AstraZeneca seeks preclusion of Dr. Genck's evidence and opinions, arguing that *Hanmi* has somehow raised a new claim construction issue. To the contrary, it is AstraZeneca who has now identified claim terms in response to the Court's Order (D.I. 269), and who seeks preclusion of Dr. Genck's opinions on those terms. It would be an anomalous and unfair result if

² Ironically, AstraZeneca had already prevailed on its proposed construction of "solid-state" as meaning "a solid material." AstraZeneca never argued for a construction of "solid-state" as including hydrates prior to Prof. Byrn's February 19, 2013 opening report. Thus, Dr. Byrn's statement that "solid state" and "alkaline salts [of esomeprazole]" included hydrates was AstraZeneca's second proposed claim constructions for those terms in this case.

AstraZeneca were permitted to introduce a *second* proposed claim construction for "solid state" and "alkaline salts [of esomeprazole]" in its opening expert reports, but Hanmi's experts were not provided a fair opportunity to respond to those new arguments.

With respect to the substance of its "claim construction" argument, AstraZeneca continues in its failure to recognize any distinction between claim term construction and the breadth of claim scope as it relates to the public notice function. *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1358 (Fed. Cir. 2005) ("The ability to discern both what has been disclosed and what has been claimed is the essence of public notice. It tells the public which products or processes would infringe the patent and which would not."); *see also Southwall Tech., Inc., v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995).

Dr. Genck's analysis is directed to the scope of the claims as informed by the record evidence in this case. Any suggestion that Dr. Genck has engaged in claim term construction exercise with respect to any particular claim term (such being ultimately resolved by the Court) is without basis. Dr. Genck has not sought to construe or interpret any claim term – indeed he has not even identified a claim term in need of construction or offered any construction of any claim term. There are simply no claim terms to construe in any asserted claim that pertain to hydrates. Rather, Dr. Genck considered the overall breadth of the claims as failing to encompass hydrated compounds, concluding that – in view of the case record and the unpredictability of formation and properties of hydrated compounds – a person of ordinary skill in the art would not expect the claims as construed to encompass hydrated forms absent an express recitation of them as such. (*See, e.g.,* Rebuttal Report of Wayne Genck, served March 25, 2013 (D.I. 290-11), ¶¶ 30-31).

Dr. Genck is not a lawyer and has never purported to be a lawyer. In forming his opinions, Dr. Genck considered and analyzed the case record according to his views as an expert in pharmaceutical chemistry. Dr. Genck made clear to AstraZeneca that he accepted the Court's construction of claim terms and that he had considered the scope of the '504 and '192 patents according to a person of ordinary skill in the art. (*See, e.g.*, Ex. 5, April 25, 2013 Deposition of Wayne Genck, pp. 47-49 (discussing how a person of ordinary skill in the art would interpret the '504 patent with regard to formation of hydrated compounds)). He did not provide a legal interpretation of any claim term. *See id.* Dr. Genck's consideration of the scope of the patents and claims at issue from the perspective of one of ordinary skill presents no basis for AstraZeneca's request for additional *Markman* discovery (*see* D.I. 293, pp. 7-8), as Dr. Genck has based his March 25, 2013 analysis solely on the case record developed to date.

Relying on his October 7, 2011, Declaration and his analysis of the disclosures of the '504 and '192 patents and related 6,369,085 ("085") and 7,411,070 ("070") patents and their prosecution histories (*see* October 7, 2011 Genck Decl. (D.I. 108), ¶¶ 74-101), Dr. Genck has now demonstrated in his second report, having considered the full record, that a person of ordinary skill in the art would not consider the scope of '504 and '192 patent claims to cover hydrated forms of (-)-omeprazole salts (*See* Rebuttal Report of Wayne Genck, served March 25, 2013 (D.I. 290-11), ¶¶ 27-79, 83-101).

II. Dr. Genck's Non-Infringement Theories are Not Surprising or Prejudicial to AstraZeneca

AstraZeneca was neither surprised nor prejudiced by Dr. Genck's non-infringement positions. As discussed above, Dr. Genck's opinions on non-infringement rely on the well-established record of Hanmi's Motion for Summary Judgment No. 4, including AstraZeneca's

opposition, and the Court's ruling on Motion 4, as well as Hanmi's Second Amended Contentions, expressly permitted by the Court. In fact, in Hanmi's motion to amend its contentions, Hanmi expressly disclosed to AstraZeneca that it was "conforming its present contentions (sent in draft to AstraZeneca on October 11, 2012) to the existing summary judgment record." (*See* D.I. 238-1, p. 3). AstraZeneca has known of Hanmi's non-infringement position long before the filing of expert reports.

To the extent that Dr. Genck's non-infringement analysis in his second report extends beyond the summary judgment record, such analysis directly responds to AstraZeneca's new infringement theory presented in Prof. Byrn's opening expert report that "solid state" is the claim term through which provides hydrated compounds are included within the scope of the '504 patent. (*See, e.g.*, Expert Report of Stephen R. Byrn, served February 19, 2013 (D.I. 294-2), ¶¶ 111-117). AstraZeneca cannot legitimately assert that Hanmi's response to AstraZeneca's untimely infringement theories caused it surprise.

Similarly, AstraZeneca is not prejudiced by the disclosure of Dr. Genck's non-infringement positions in his second report. AstraZeneca has long known Hanmi's position on non-infringement, and any additional discussion in Dr. Genck's second expert report was responsive to AstraZeneca's new theories on "solid state" presented in Prof. Byrn's opening expert report. (*See, e.g.*, Report of Stephen R. Byrn (D.I. 294-2), ¶¶ 111-117).

In addition, AstraZeneca has had ample opportunity to address Dr. Genck's responsive analysis. AstraZeneca's reply report of Prof. Byrn focused on Dr. Genck's non-infringement theories, including whether the scope of "solid state" includes hydrated compounds. (*See* Prof. Byrn's Reply Report (D.I. 294-10), ¶¶ 7-80.) Nowhere in Prof. Byrn's reply report did he express any inability to completely respond to Dr. Genck's non-infringement views. Nowhere did Prof.

Byrn state that he had insufficient facts, documents, or opportunity to fully respond to Dr. Genck's views. Nowhere did he state that his rebuttal of Dr. Genck's views was incomplete, or less informed than it could have been. AstraZeneca had ample opportunity to cross-examine Dr. Genck about his analysis of "solid state" scope at Dr. Genck's April 25, 2013 deposition, and did so. (*See, e.g.*, Ex. 5, April 25, 2013 Deposition Transcript of Wayne Genck, pp. 24-47.) AstraZeneca will also have the opportunity to cross-examine Dr. Genck at trial. AstraZeneca claims prejudice, but cannot demonstrate it.³ Indeed, exclusion of Dr. Genck's testimony and permitting Prof. Byrn's testimony to go unanswered would result in in unfair prejudice to Hanmi, not to AstraZeneca.

III. Dr. Genck's Testimony Will Be Helpful to the Court

Dr. Genck's opinions and evidence on non-infringement will aid the Court and should be considered. (*See* Fed. R. Evid. 702). In his second expert report, Dr. Genck concludes that because of the unpredictability of formation and properties of hydrated compounds, a person of ordinary skill in the art would expect claims directed to hydrated compounds to expressly recite such forms. (*See, e.g.*, Rebuttal Report of Wayne Genck (D.I. 290-11), ¶¶ 30-31.) Dr. Genck's analysis of "solid state" as it applies to hydrated compounds therefore is necessary to provide the trier of fact a comprehensive view of the parties' positions on this important point.

Because this is a bench trial, presentation of the parties' conflicting positions will not raise a concern of confusing the trier of fact. Furthermore, if the Court allows AstraZeneca to

³ AstraZeneca's assertion that Dr. Genck's non-infringement analysis is vague and unexplained, with which Hanmi disagrees, does not warrant preclusion of Dr. Genck's testimony. AstraZeneca had clear notice of Hanmi's non-infringement contentions; at best, AstraZeneca's arguments go to the weight of Dr. Genck's testimony. *See First Tenn. Bank Nat'l Ass'n v. Barreto*, 268 F.3d 319, 333 (6th Cir. 2001) (questions relating to the bases of an expert's opinion generally affect the weight to be given the testimony, not its admissibility, and are left for the fact finder's consideration).

present its theory on "solid state" (*see* Hanmi's Motion *in Limine* No. 2, D.I. 290-2), consideration of Hanmi's position will promote orderly and efficient judicial proceedings. This result also promotes fairness and justice; AstraZeneca should not be rewarded for waiting until its expert reports to introduce its theories of infringement into the case.

IV. Conclusion

For the foregoing reasons, Hanmi respectfully requests that AstraZeneca's motion be denied.

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CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2013, I caused a copy of the foregoing **Hanmi's Motion In Opposition to Plaintiff's Motion to Preclude Hanmi's Expert Dr. Genck From Relying On Certain Non-Infringement Opinions and Evidence Concerning "Hydrates"** to be served upon the following counsel by electronic mail:

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